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ATTORNEY DOCKET NO. CONFIRMATION NO.
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APPLICATION NO.

09/806,635

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09/17/2003

FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198

FILING DATE

06/04/2001

EXAMINER

PAPER NUMBER

ANDRES, JANET L

ART UNIT

1646 DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FIRST NAMED INVENTOR

Carola Dony

	Application No.	Applicant(s)
Office Action Summary		
	09/806,635	DONY ET AL.
	Examiner	Art Unit
	Janet L. Andres	1646
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet w	vith the correspondence address
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	36(a). In no event, however, may a y within the statutory minimum of th will apply and will expire SIX (6) MC , cause the application to become A	reply be timely filed irty (30) days will be considered timely. NTHS from the mailing date of this communication. NBANDONED (35 U.S.C. § 133).
1)⊠ Responsive to communication(s) filed on <u>24 June 2003</u> .		
	is action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims	andina in the application	
4) Claim(s) 18-20,22-24,27-29 and 33-37 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>18-20,22-24,27-29,33-37</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers		
9) The specification is objected to by the Examine	r	
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C.	§ 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  a) The translation of the foreign language provisional application has been received.		
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152)

### RESPONSE TO AMENDMENT

1. Applicant's amendment filed 24 June 2003 and declaration filed 25 August 2003 are acknowledged. Claims 18-20, 22-24, 27-29, and 33-37 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

# Claim Rejections/Objections Withdrawn

2. The rejection of claims 18-20, 22-24, 27-29, and 33 under 35 U.S.C. 112, first paragraph, as lacking enablement or written description is withdrawn in response to Applicant's amendment and declaration under rule 132.

# Claim Rejections Maintained/New Grounds of Rejection

3. Claim 35 is rejected under 35 U.S.C. 103(a) as unpatentable over the '366 patent in view of the '929 patent or the 1992 BioRad catalogue for reasons of record in the office action of 25 March, 2003.

Applicant argues that the fact that an antigenic protein can be combined with a matrix does not lead one to incorporate MIA into such a matrix.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the previous office action, the '366 patent teaches that MIA can inhibit cancer cell division and the proliferation of peripheral blood lymphocytes. Thus, it teaches that MIA has useful properties. It further teaches that it is desirable to produce such antibodies. The '929 patent teaches matrices for the production of antibodies. Thus, one of ordinary skill in the art, aware of the teachings of the '366 patent and the '929 patent, would know that combining MIA with matrices would be a useful way of producing antibodies to MIA, and would know

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from the '366 patent that it would be desirable to produce antibodies to MIA. Motivation to combine the two teachings is provided by the statement in the '366 patent that it is desirable to produce such antibodies. Similarly, the '366 patent teaches that MIA is useful, and the BioRad catalogue teaches means to obtain purified proteins. Heparin and hydroxyapatite are widely used for purification of proteins, as is taught by the BioRad catalogue, and thus it would be obvious to the artisan of ordinary skill to use them for this purpose.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20, 22-24, 27-29, and 33-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are drawn to methods and compositions requiring "a melanoma inhibiting activity factor". The melanoma inhibiting activity factor MIA is well known in the art; however, there is no definition in the specification for "a melanoma inhibiting activity factor" and one of skill in the art would be unable to determine what molecules Applicant intended the claims to encompass. It is suggested that language such as "the melanoma inhibiting activity factor MIA" might overcome this rejection.

### NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D. September 16, 2003

PATENT EXAMON